510 (k) Summary

K083066

Submitter:

BERCHTOLD Holding GmbH
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Germany

OCT 30 2008

Contact Person:

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Regulatory Affairs
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Preparation Date: September 17, 2008

Trade Name: CHROMOPHARE® E 778
CHROMOPHARE® E 558

Common Name: Surgical lamp

Classification Name: Light, Surgical, Ceiling mounted

Predicate Device: BERCHTOLD CHROMOPHARE® E 655 (K080857)

Device Description: The new BERCHTOLD CHROMOPHARE® E 778 and E 558 surgical lights are suitable for all types of surgical procedures. With the use of Light Emitting Diodes (LEDs) in these lights, BERCHTOLD realizes high illumination intensity with a lower heat radiation and less pattern variation compared to previous generations of BERCHTOLD products. The light features easy-to-operate swivel arms. Each light functions with an optional integrated CCD video camera and/or with upward "EndoLite" and/or with downward "GuideLite" for endoscopic procedures. The lights could be combined among each other.

Intended Use of the device: The CHROMOPHARE® E 778 and E 558 is intended to be used to provide visible illumination to the surgical field of the patient.

Indications for Use: The surgical lights BERCHTOLD CHROMOPHARE® E 778 and E 558 are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Summary of technological characteristics compared to the predicate device:

The BERCHTOLD CHROMOPHARE® E 778 & E 558 are substantially equivalent to the surgical lights BERCHTOLD CHROMOPHARE® E 655 (K080857). Similarities and differences are tabulated below. Any differences between the CHROMOPHARE E 778 / E 558 and the predicate device do not alter the safety or efficacy of the device.

	Legally marketed device CHROMOPHARE® E 655	**New devices** CHROMOPHARE® E 778	CHROMOPHARE® E 558
Intended use	Illumination of the operating site on a patient's body	Same	Same
Input power	120V, 1- phase lines, 60Hz	Same	Same
Protection against electrical shock	Class I	Same	Same
Diameter of light body	649mm	763mm	568mm
Diameter of reflectors	Polygon reflector: 520mm	84 reflectors: 35mm 84 reflectors: 40mm	36 reflectors: 35mm 36 reflectors: 40mm
Number of mirrored reflector elements	720	None	None
Lamp technology	Metal halide discharging	Light Emitting Diode	Light Emitting Diode
Reflector	single-piece polygon reflector	168 individual reflectors	72 individual reflectors
Power consumption of bulb	72W	<2W each	<2W each
Light / heat filter technology incl. UV light filter mechanism	ThermoSorb®	None	None
Color rendering index R_a	94	same	same
Color temperature	4300°K	3600K, 4000K, 4500K, 5000K	3600K, 4000K, 4500K, 5000K
Central illuminance (at 1m)	80000 – 160000lux	same	70000 - 140000lux
Light field diameter	170 – 280mm	140 – 285mm	140 - 285mm
Depth of illumination	1300mm	690mm	805mm
Total irradiance E_e	560W/m²	505W/m²	442W/m²
UV- irradiance (≤400nm)	2.0W/m²	0	0
Light focusing mechanism	Rotating of Handle	Pressure Sensitive Handgrip	Pressure Sensitive Handgrip
Life time of bulb	5000h	20000h	20000h
Automatic switching to the reserve bulb	Yes	No	No
Bulb replacement indicator	Yes	No	No
Reusable steam sterilizable lamp handle	Yes	Same	Same
Additional light controls in separate wall box	Standard	Same	Same
Ambient illumination for minimally invasive surgeries	Optional upward "EndoLite"	Optional upward "EndoLite" and/or downward "GuideLite"	Optional upward "EndoLite" and/or downward "GuideLite"
CCD video camera located in sterilizable lamp handle	Optional feature	Same	Same

Performance Summary:

This device conforms to IEC 60601-2-41:2001 specifications for performance of surgical lamps. This device conforms to IEC 60601-1 and IEC 60601-1-2 for electrical safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 2008

Berchtold Holding GmbH
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K083066
Trade/Device Name: CHROMOPHARE® E 778
CHROMOPHARE® E 558
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: October 13, 2008
Received: October 15, 2008

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

CHROMOPHARE® E 778
CHROMOPHARE® E 558

Indications for Use:

The surgical lights BERCHTOLD CHROMOPHARE® E 778 and E 558 are intended to illuminate locally the operating site on the patient's body with a high intensity, shadow free, "cold" light.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083066